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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,381	04/15/2004	G. Ian Rowlandson	146461 (5024-00123)	8457

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EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/825,381

Applicant(s)

ROWLANDSON ET AL.

Examiner

Carl H. Layno

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-28 is/are allowed.
- 6) ☒ Claim(s) 1,3 and 8-10 is/are rejected.
- 7) ☒ Claim(s) 2,4-7 and 11-13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/15/04, 5/26/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449), which was received by the Office on April 15, 2004 and May 26, 2004.

### ***Drawings***

2. Applicant's formal drawings were received by the Office on April 15, 2004 and have been approved by the Examiner.

### ***Specification***

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In this case, applicant should refrain from using the language "the invention" in line 2 of the Abstract..

### ***Claim Rejections - 35 USC § 102***

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by the Tateishi et al article “Observation of sleep-related breathing disorders in patients with coronary artery disease by ambulatory electrocardiogram-respiration monitoring system” (Jpn Circ J, 1994 Nov; 58(11):831-835).

The Tateishi et al article “Observation of sleep-related breathing disorders in patients with coronary artery disease by ambulatory electrocardiogram-respiration monitoring system” (Jpn Circ J, 1994 Nov; 58(11):831-835) describes a study whose conduct appears to read upon the method steps claimed by the applicant. Specifically, the abstract describes a study involving 85 coronary artery patients who were examined using ambulatory electrocardiogram-respiration monitoring systems (AERMS) in which both respiratory sensors and ECG sensors were attached to the patients. Data from these sensors were used to diagnose 9 patients with sleep-related breathing disorders (SRBDs) (i.e. patients suffering more than 30 Apneic episodes during a sleeping period). Follow up studies were conducted on these patients including occurrence of “sudden death, myocardial infarction, and ventricular tachyarrhythmia”. Following a period of about 18 months, it was statistically shown that 44% of patients in the SRBD group experienced cardiac events compared to 6% of the non-SRBD patients.

In regard to claims 3, 8, and 9, the Tateishi et al equipment monitors/calculates ejection fraction (EF) and can determine when  $EF < 50\%$  (Abstract, line 9). In addition, the respiratory sensor is strapped to “the right upper abdominal wall” to sense motions (Abstract, line 3).

In regard to claim 10, patients were diagnosed as having sleep-related breathing disorders (SRBDs) if they suffered more than 30 Apneic episodes during a sleeping period (each apneic episode corresponding to a lack of respiratory wall movement for a period of at least 10 seconds) (Abstract, lines 4-5).

*Allowable Subject Matter*

6. Claims 2, 4-7, and 11-13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 14-28 are allowed.

8. The following is a statement of reasons for the indication of allowable subject matter:

Independent claims 14, 22, 27, and 28 describe a computer program and corresponding device claims, respectively, involving a device for monitoring sleep apnea and a risk of sudden cardiac death. Unlike the AERMS device described by the Tateishi et al article (cited supra), the applicant’s device includes an integrated “patient data acquisition system” or “means” for determining a “correlation between sleep apnea and a risk of sudden cardiac death”. Whereas, the Tateishi et al article appears to calculate this relationship by hand after a long observation

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period. Consequently, the Examiner deems these claims and their depending claims to be allowable.

### *Conclusion*

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


The Forbes (US 5,187,657) patent describes a device capable of monitoring ECG and respiration data for determining a patient's susceptibility to sudden cardiac death (Abstract, line 18) and to sleep apnea (col.7, lines 50-52). Unlike applicant's device, that of Forbes does not attempt to define the relationship between sleep apnea and sudden cardiac death.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CARL LAYNO  
PRIMARY EXAMINER

CHL  
6/30/2006